

# Chapter 10

# Cleaning, Disinfection and Sterilisation

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## Key points

- The failure to disinfect or sterilise medical equipment properly may result in infection.
- The level of decontamination required depends upon the intended use of the item.
- Cleaning is essential before disinfection or sterilisation.
- Chemical disinfection must be used only when required by written policies.
- Thermal decontamination is safer and more effective than chemical.
- Steam sterilisation is effective only when preceded by cleaning and carefully monitored.
- Staff members responsible for processing contaminated devices must be fully trained and wear protective apparel.

## Introduction

Contaminated medical equipment and instruments can transmit infection to both patients and staff, so they must be effectively decontaminated after each use. Devices that cannot be properly cleaned and decontaminated (e.g., injection needles), must be 'single use', and not re-processed. Decontaminated items must be protected from contamination or damage during storage.

Earle H. Spaulding<sup>1</sup> categorised equipment as: critical, semi-critical and non-critical according to the degree of risk of infection from their use:

**Critical items** are those that enter sterile tissues, including body cavities, and the vascular system, e.g., surgical instruments and vascular catheters. Any microbial contamination (including bacterial spores) presents a high risk of infection if such an item is contaminated, so they must be cleaned and sterilised before use.

**Semi-critical items** are those that come into contact with intact mucous membranes or broken skin, such as respiratory equipment, gastrointestinal endoscopes, vaginal instruments, and thermometers. These should be free from vegetative microorganisms (i.e., mycobacteria, fungi, viruses, bacteria), although small numbers of bacterial spores are acceptable. Semi-critical items require cleaning followed by a minimum of high-level disinfection.

**Non-critical items** such as bedpans, blood pressure cuffs, ear examination funnels, and patient furniture present a low risk of infection from contact with normal skin. Such items (sometimes called 'fomites') could contribute to the spread of infection via staff hands or contact with other medical equipment. Cleaning is usually adequate, but may be followed by low-level disinfection.

Staff responsible for processing contaminated equipment should:

- Have received adequate training
- Wear appropriate protection - gloves, gowns or aprons, and splash protection (mask and goggles, or visor)
- Receive adequate immunisations

## Cleaning

Cleaning removes organic soil (blood, etc.) and reduces the bacterial load about 1000 fold or more. Organic soil protects microbes from disinfection and sterilisation processes, and so items must be thoroughly cleaned *before* processing.

Cleaning processes may involve chemical energy (detergents or enzymes), mechanical energy (friction), or thermal energy. Cleaning can be manual or by use of washing/washer disinfectant machines or ultrasonic cleaners.

Manual cleaning requires a neutral detergent and friction to remove soil from the surface of instruments. Cleaning-disinfecting agents, also known as 'two-in-one' products, may be used for manual processing of instruments. Washing machines require an alkaline detergent to make up for the lack of friction. Soil remains in the cleaning solution of an ultrasonic nebuliser – so instruments must be rinsed after processing.

Items must be disassembled and cleaned as soon as possible after use to prevent soil drying on them. Scissors and forceps require opening to allow contact with cleaning agents. Rinsing is needed to remove residual chemicals, and then drying is important to prevent moisture from interfering with further processing, or allowing re-contamination.

## Processing

### Disinfection

Disinfection reduces the number of pathogenic microbes (except bacterial spores) to a level that is not harmful to human health. This can be achieved by heat or chemicals.

#### Thermal (heat) disinfection

Heat is preferable to chemicals, and can be combined with cleaning in a washer (flusher) disinfectant. Standard specifications for such machines are available.<sup>2</sup> The machine cycle must start with a low-temperature rinse to remove soil, which is followed by exposure to 85°C for 15 minutes. Machines require electricity and a reliable water supply. Times and temperatures of exposure must be monitored, and machines require regular maintenance and validation. Pasteurisation is another

thermal process, which involves exposure to  $>70^{\circ}\text{C}$  ( $158^{\circ}\text{F}$ ) for 30 minutes in a water bath. This is useful for respiratory and anaesthetic equipment. All items must remain in contact with the hot water throughout the process.

### **Chemical disinfection**

Chemical disinfectants can be used alone or in combinations. They include alcohols, chlorine and chlorine compounds, glutaraldehyde, ortho-phthalaldehyde, hydrogen peroxide, peracetic acid, phenolics, biguanides, and quaternary ammonium compounds. Many commercially available formulations based on these chemicals are available; the labels should be read carefully to ensure that the right product is selected and used efficiently. Disinfectants are designed to harm living cells and are thus harmful to staff. They may damage the environment and are expensive, so chemical disinfection should only be used when absolutely necessary.

Chemical disinfectants are categorized according to spectrum of activity into high-level, intermediate level and low level. They are tested by standardised processes as to their activity in suspension and in carrier tests.<sup>2</sup>

**High-level disinfectants** kill all viruses and vegetative bacteria; they may not reliably kill spores (unless used for long exposure times). They are used for heat sensitive semi-critical items such as endoscopes. Aldehydes such as glutaraldehyde or ortho-phthalaldehyde are commonly used high-level disinfectants. They also fix proteins, thus protecting microbes. Items must be made protein-free by careful cleaning before disinfection. Per-acids, peroxides and other oxidizing agents, e.g., 0.2–0.35% peracetic acid or 6–7.5% hydrogen peroxide are more effective than aldehydes in the removal of biofilms, and also less harmful to the environment as they can be readily inactivated. A recent addition is a stabilised chlorine dioxide.

High-level disinfection requires 10–45 minutes exposure to disinfectant at  $20\text{--}26^{\circ}\text{C}$ ; longer exposures are required to achieve sterilisation. After disinfection items such as endoscopes require rinsing with sterile or filtered water to remove any residual disinfectant. They can then be dried with an alcohol rinse.

**Intermediate-level disinfectants** destroy all vegetative bacteria including mycobacteria, fungi and most but not all viruses. They do not kill endospores even with prolonged exposure.

**Low-level disinfectants** only destroy fungi, vegetative bacteria (except mycobacteria), and enveloped viruses.

Table 10.1 shows the most commonly used chemical disinfectants in health care facilities.<sup>3,4</sup>

## **Sterilisation**

Sterilisation is used to render an object free from all viable agents including bacteria, viruses and bacterial spores (though not necessarily prions).<sup>5</sup> The degree of sterility can be measured by the probability of a single product remaining contaminated after the process. This is called the 'Sterility Assurance level' (SAL). SAL is expressed as  $10^n$ , for example if the probability of a single product remaining unsterile is one in a million, the SAL is  $10^6$ . This is the generally accepted SAL, although this is an empirical value and not supported by documented adverse effects (patient infections).

Heat is the most reliable sterilant; fortunately most medical devices are made from heat-resistant material. Heat is usually applied by transfer of latent heat from steam under pressure in an autoclave, which denatures microbial proteins. Dry heat in an oven is needed for materials such as powders that may be damaged by moisture, or those which steam cannot penetrate, such as oils and waxes. Dry heat works by oxidation and is a much slower process.

Heat sensitive items (usually those containing plastics such as polythene) require low-temperature sterilisation. Low temperature sterilising processes include ethylene oxide gas, hydrogen peroxide gas-plasma, and chemicals such as the aldehydes.

Sterilisation processes are determined by their D-value: the 'decimal reduction time'. This is the process time required for a 1 log reduction in microbial count (90%). So if the D-value for a steam steriliser is 1 minute at  $121^\circ\text{C}$ , and you have  $10^2$  spores, then after 1 minute you should have  $10^1$  spores, and to reach a SAL of  $10^6$  you will need 8 minutes exposure. If the bioburden (contamination) on the device is high, some

**Table 10.1.** The most widely used chemical disinfectants in healthcare

Agents	Spectrum	Uses	Advantages	Disadvantages
<p>Alcohols (60-90%) including ethanol or isopropanol</p>	<p>Low to intermediate level disinfectant</p>	<p>Used for some semicritical and noncritical items, e.g. oral and rectal thermometers and stethoscopes. Also to disinfect small surfaces such as rubber stoppers of multi-dose vials. Alcohols with detergent are safe and effective for spot disinfection of countertops, floors, and other surfaces.</p>	<p>Fast acting. No residue. No staining. Low cost. Readily available in all countries.</p>	<p>Volatile, flammable, and irritant to mucous membranes. Inactivated by organic matter. May harden rubber, cause glue to deteriorate, or crack acrylic plastic.</p>
<p>Chlorine and chlorine compounds: the most widely used is an aqueous solution of sodium hypochlorite 5.25-6.15% (house bleach) at a concentration of 100-5000 ppm free chlorine</p>	<p>Low to high level disinfectant</p>	<p>Used for disinfecting tonometers and for spot disinfection of countertops and floors. Can be used for decontaminating blood spills. Concentrated hypochlorite or chlorine gas is used for disinfection of large and small water distribution systems such as dental appliances, hydrotherapy tanks, and water distribution systems in haemodialysis centres.</p>	<p>Low cost, fast acting. Readily available in most settings. Available as liquid, tablets or powders.</p>	<p>Corrosive to metals in high concentrations (&gt;500 ppm). Inactivated by organic material. Causes discoloration or bleaching of fabrics. Releases toxic chlorine gas when mixed with ammonia. Irritant to skin and mucous membranes. Unstable if left uncovered; exposed to light or diluted; store in opaque container.</p>

Agents	Spectrum	Uses	Advantages	Disadvantages
<p>Aldehydes</p> <p>Glutaraldehyde: ≥2% aqueous solutions buffered to pH 7.5-8.5 with sodium bicarbonate.</p> <p>Novel Glutaraldehyde formulations include: glutaraldehyde-phenol-sodium-phenate, potentiated acid glutaraldehyde and stabilized alkaline glutaraldehyde</p>	<p>High level disinfectant/sterilant</p>	<p>Most widely used as high-level disinfectant for heat sensitive semicritical items such as endoscopes (for 20 minutes at 20°C).</p>	<p>Good material compatibility.</p>	<p>Allergenic and its fumes are irritating to skin and respiratory tract.</p> <p>Causes severe injury to skin and mucous membranes on direct contact.</p> <p>Relatively slow activity against some mycobacterial species.</p> <p>Must be monitored for continuing efficacy levels.</p>
<p>Peracetic acid</p> <p>0.2-0.35% and other stabilised organic acids</p>	<p>High level disinfectant/sterilant</p>	<p>Used in automated endoscope reprocessors. Can be used for cold sterilisation of heat sensitive critical items, e.g., haemodialysers.</p> <p>Also suitable for manual instrument processing [depends on formulation].</p>	<p>Rapid sterilization cycle time at low temperature (30-45 min. at 50-55°C).</p> <p>Active in presence of organic matter.</p> <p>Environment friendly by-products (oxygen, water, acetic acid)</p>	<p>Corrosive to some metals.</p> <p>Unstable when activated.</p> <p>May be irritating to skin, conjunctive and mucous membranes.</p>

Agents	Spectrum	Uses	Advantages	Disadvantages
Orthophthalaldehyde (OPA) 0.55%	High level disinfectant/sterilant	High level disinfectant for endoscopes.	<p>Excellent stability over wide pH range, no need for activation.</p> <p>Superior mycobactericidal activity compared to glutaraldehyde.</p> <p>Does not require activation.</p>	<p>More expensive.</p> <p>Stains skin and mucous membranes. May stain items not thoroughly cleaned.</p> <p>Eye irritation with contact.</p> <p>May cause hypersensitivity reactions in cancer bladder patients following repeated exposure to manually processed urological instruments.</p> <p>Slow sporicidal activity.</p> <p>Must be monitored for continuing efficacy levels.</p>
Hydrogen peroxide 7.5%	High level disinfectant/sterilant	<p>Can be used for cold sterilization of heat sensitive critical items.</p> <p>Requires 30 minutes at 20°C.</p>	<p>No activation</p> <p>No odour.</p> <p>Environment friendly by-products (oxygen, water).</p>	<p>Material compatibility concerns with brass, copper, zinc, nickel/silver plating.</p>
Hydrogen peroxide 7.5% and peracetic acid 0.23%	High level disinfectant/sterilant	For disinfecting haemodialysers	<p>Fast acting (high level disinfection in 15 min.).</p> <p>No activation required.</p> <p>No odour.</p>	<p>Material compatibility concerns with brass, copper, zinc, and lead.</p> <p>Potential for eye and skin damage.</p>

Agents	Spectrum	Uses	Advantages	Disadvantages
Glucoprotamin	High level disinfectant	Manual reprocessing of endoscopes. Requires 15 minutes at 20°C.	Highly effective against mycobacteria. High cleansing performance. No odour.	Lack of efficacy against some enteroviruses and spores.
Phenolics	Low to intermediate level disinfectant	Have been used for decontaminating environmental surfaces and non-critical items. Should be avoided.	Not inactivated by organic matter.	Leaves residual film on surfaces. Harmful to the environment. No activity against viruses. Use in nurseries should be avoided due to reports of hyberbilirubinemia in infants.
Iodophores (30-50 ppm free iodine)*	Low level disinfectant	Have been used for disinfecting some non critical items, e.g., hydrotherapy tanks, however it is used mainly as an antiseptic (2-3 ppm free iodine).	Relatively free of toxicity or irritancy.	Inactivated by organic matter. Adversely affects silicone tubing. May stain some fabrics.
Quaternary ammonium compounds*	Low level disinfectant	Used mainly on environmental surfaces. Can be used as a skin antiseptic.	Stable and has good detergent properties (cationic detergent). Usually non-irritating.	Has relatively narrow microbicidal spectrum, but range of activity can be expanded when combined with other disinfectants, e.g., alcohols. Few advantages over household detergent.

\* These chemicals are rarely recommended

sterilisation processes (for example irradiation) cannot render it sterile. Thus cleaning is essential before a device is packed for sterilisation.

### **Steam sterilisation**

This is the most widely used method of sterilisation. It is non-toxic, has good penetrating ability, is relatively inexpensive, and can easily be monitored for efficacy.

Steam sterilisation requires exposure to direct steam contact at a required temperature and pressure for a specified time. Pressurized steam sterilisers (autoclaves) are fed with steam under pressure; thus high temperatures are produced.

There are two basic mechanisms of steam sterilisers:

- Gravity (downward) displacement in which steam is introduced at the top of the chamber, the cooler and denser air-steam mixture and any condensate is discharged by gravity from the bottom of the chamber. The exhaust has a 'near to steam' valve, which closes when all the air has been removed, and allows pressure to build up. This type of steriliser is being phased out, but some are still in use for unwrapped instruments and fluids. The sterilising hold time is 15 minutes at 121°C at 1.036 Bar (15.03 psi).
- Porous load (pre-vacuum) sterilisers are fitted with a vacuum pump to remove the air from the sterilising chamber before the chamber is pressurized with steam. To ensure complete air removal, the pump is operated for several cycles, with repeated injections of steam. They allow faster and more positive steam penetration throughout the entire load. This type of steriliser usually has a 'holding time' of 3 minutes at 134°C at 2.026 Bar (29.41 psi).

As heat is generated only on surfaces where steam can condense, the autoclave load must be placed so that steam can reach all packages.

Items should be packaged in materials such as paper and/or polymers that can be penetrated by steam and still keep the items sterile during storage. Packages must be marked to identify their contents, date of sterilisation, and steriliser and load number. This helps to facilitate

recall action and to aid in rotation of supplies.

Autoclaves must be tested before being used and regularly thereafter. Users must be trained on autoclave operation and safety, and keep a written record of maintenance.

There are two approaches to checking that a sterilising cycle has worked - product testing or parametric release. If you have an SAL of  $10^6$  you cannot test a million items for sterility – so instead biological indicators (spore tests) can be used. They assess the process directly by killing known highly resistant microorganisms (*Geobacillus stearothermophilus*). Autoclaves should be tested at least weekly using a biological indicator. Biological indicator results take up to 3-7 days, which is often too long for quarantine of devices run in the process. Spore strips must be obtained from a reputable supplier and their use requires a laboratory facility.

Chemical indicators can also be used to assess physical conditions (e.g., time and temperature) during the sterilisation process. They include external chemical indicators applied to the outside of a package (e.g., chemical indicator tape) or internal indicators. Autoclave tape on the outside of the package only shows if the package has been exposed to heat and is not a process indicator. Chemical indicators change colour rapidly when a specific parameter is reached and they verify that the package has been exposed to the sterilisation process. Although chemical indicators do not prove sterilisation has been achieved, they allow detection of certain equipment malfunctions and they can help identify procedural errors.

The alternative approach is 'parametric release'. This relies on ensuring that the autoclave cycle has fulfilled the specifications with regard to temperature, pressure and time using calibrated instruments instead of biological microorganisms. Since this approach is based on measurable data and calibrated equipment, the results tend to be more reliable. One important function is removal of all air and non-condensable gases from the autoclave, so allowing proper penetration of steam throughout the load.

Air removal in a high-vacuum steriliser can be monitored in two ways – firstly by a 'leak test': can the vacuum be held or will air leak in (often

around the door), and secondly by the ability of steam to penetrate into a small load such as the small pack of towels used in the 'Bowie-Dick' test. If these results are satisfactory then each cycle of the autoclave should have the pressure, temperature (in the drain) and time recorded. If all three are satisfactory the load can be 'parametrically' released, without the need for biological indicators.

Sterilised items must be stored appropriately. Packages containing sterile supplies should be inspected before use to verify barrier integrity and dryness. If packaging is compromised, the instruments should be re-cleaned, packaged in new wrap, and sterilised again.

Small, portable steam sterilisers are used in certain healthcare settings, e.g., outpatient and dental clinics. These sterilisers are designed for small instruments, such as dental instruments. They should also be monitored by mechanical, chemical, and biological indicators.

Flash sterilisation is a method for sterilising unwrapped patient-care items for immediate use (often used for dropped instruments in operating theatres). Disadvantages of flash sterilisation include: the lack of timely biological indicators to monitor performance, absence of protective packaging following sterilisation, and possibility for contamination of processed items during transportation to the point of use. Some rigid, reusable sterilisation container systems have been designed and validated by the container manufacturer for use with flash cycles. Care should be taken to avoid thermal injury to personnel during transportation of flash sterilised items to the point of use.

### **Dry heat sterilisation**

Dry heat sterilisation can be achieved in a hot air oven equipped with fan or conveyor which will ensure even distribution of heat. It can be used for glassware, powders and anhydrous material like oil and grease. Sterilisation times vary according to temperature (160°C for 2 hours and 180°C for 1 hour).

### **Ethylene oxide sterilisation**

Ethylene oxide (EO) is used for sterilisation of items that cannot withstand heat, pressure or moisture. EO is a colourless gas that is flammable and explosive. The main disadvantages associated with EO are the lengthy cycle time, the cost, and its potential hazards to patients

and staff. Sterilised items must be aerated after processing to remove dissolved EO according to manufacturer's instructions.

There are four parameters that must be maintained to ensure EO sterilisation: gas concentration, temperature, humidity and exposure time. Gas concentration should be 450 to 1200 mgm/l, temperature ranges from 37 to 63°C, humidity from 40% to 80%, and exposure times from one to six hours. Parametric release is not possible as gas concentrations and relative humidity cannot readily be measured, and so a biological indicator should be included with each load. The recommended biological indicator is *Bacillus atrophaeus*. This implies that loads must be quarantined for several days to allow growth of the indicators.

Two EO gas mixtures are available. One is EO mixed with hydrochlorofluorocarbons (HCFC). HCFCs are approximately 50-fold less damaging to the earth's ozone layer than are CFCs. The other mixture is EO-carbon dioxide (CO<sub>2</sub>) mixture consisting of 8.5% EO and 91.5% CO<sub>2</sub>. This mixture is less expensive than EO- HCFC.

### **Hydrogen peroxide gas plasma**

Gas plasmas have been referred to as the fourth state of matter (i.e., liquids, solids, gases, and gas plasmas). Gas plasmas are generated in an enclosed chamber under deep vacuum using radio frequency or microwave energy to excite hydrogen peroxide gas molecules and produce charged particles, many of which are in the form of free radicals (e.g., hydroxyl and hydroperoxyl).

Gas plasma can be used to sterilise materials and devices that cannot tolerate high temperatures and humidity, such as some plastics, electrical devices, and corrosion-susceptible metal alloys. The biological indicator used with this system is *Geobacillus stearothermophilus* spores. Advantages of this method include: safety, no aeration necessary, items may be used immediately after processing or stored for later use. However, gas plasma is not designed for use on cellulose-based products such as linen and paper, and it is not useful for dead-end lumens, powders or liquids or certain lumen lengths and diameters.

Disadvantages of this system include high cost and need for special packing material since paper or linen cannot be used. In addition, any

liquid or organic residues present interrupt the process and long dead-end lumens are poorly penetrated. Nonetheless gas plasma machines are widely used, particularly for endoscope decontamination.

### **Chemical sterilisation**

Chemical sterilisation should only be used as a last resort. Before deciding to use a chemical sterilant, consider whether a more appropriate method is available. Chemical sterilants are primarily used for heat-labile equipment where single use is not cost effective. Instruments and other items can be sterilised by soaking in a chemical solution followed by rinsing in sterile water. The immersion time to achieve sterilisation or sporicidal activity is specific for each type of chemical sterilant. Difficulties arise due to challenges in the need to immerse for the appropriate time, rinse with sterile water, and then transfer the device to a sterile field for use.

### **Re-processing**

Devices that are intended for single use are marked by the manufacturer with a ②. If they are re-used, the manufacturer is no longer responsible for the quality of the device. Any re-processor needs to ask five questions concerning the end status of the device to determine if reprocessing is appropriate:

- Is it undamaged and functional?
- Can it be cleaned?
- Is it sterile?
- Is it cost effective?
- Who takes the responsibility if anything goes wrong?

Only when the answers to all these questions are positive, can patient safety be guaranteed.

### **References and Further Reading**

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